

Food Safety and Inspection Service Washington, D.C. 20250

FEB 6 2002

Dr. Ueli Kihm
Director
Federal Veterinary Office
Bern-Liebefeld
Schwarzenburgstrasse 161
CH 3003 Bern
Switzerland

Dear Dr. Kihm:

The Food Safety and Inspection Service conducted an on-site audit of Switzerland's meat inspection system from March 21 through April 9, 2001. Enclosed is a copy of the final audit report. Comments received from the government of Switzerland are included as an addendum to the final report. Thank you for the clarification regarding testing for generic Escherichia coli and species verification testing. We are continuing with our equivalence determination of Switzerland's procedures for testing ready-to-eat product for Listeria monocytogenes and Salmonella species.

If you have any questions regarding the audit or need additional information, please contact me. My telephone number is 202-720-6400 and my fax number is 202-690-7990.

Sincerely,

Sany Stratmoen, Chief

Equivalence Section

International Policy Staff

Office of Policy, Program Development and Evaluation

Enclosure

Dr. Ueli Kihm 2

cc:

Benne Battig Agricultural Attaché, Embassy of Switzerland Kenneth Roberts, Minister-Counselor, U.S. Mission Andrew, Burst, Area Officer, FAS John Prucha, ADA, OPPDE, FSIS Donald Smart, Director, Review Staff Karen Stuck, Chief, IES, IPS Sally Stratmoen, Chief, ES, IPS Amy Winton, State Department Gary Stefan, ES, IPS Country File (FY2001 Audit)

FSIS:OPPDE:IPS:GStetan:mm:1/30/02:720-9971:Cover ltr. FY2001 Final Report

| <u>Clearances</u> : | <u>Initials</u> | <u>Date</u> |
|---------------------------------------|-----------------|-------------|
| Clark Danford, Acting Director | | |
| Sally Stratmoen, Chief, ES, FSIS, IPS | | |

AUDIT REPORT FOR SWITZERLAND

March 21 through April 9, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Switzerland's meat inspection system from March 21 through April 9, 2001. Six establishments certified to export meat to the United States were audited. One of these was a slaughter establishment; the other five were conducting processing operations.

The last on-site audit of the Swiss inspection system was conducted in January 2000. Five establishments (Ests. 121, 201, 205, 215, and 293) were audited. All were acceptable. The following concerns were noted during that previous audit:

- 1. HACCP implementation deficiencies included not identifying hazards reasonably likely to occur (in three of the five establishments), not identifying critical control points (two establishments); not documenting corrective actions taken (two establishments) and not conducting pre-shipment verification review (four establishments).
- 2. Inadequate control of condemned, inedible or dead-on-arrival (DOA) carcasses before off-premises shipment.
- 3. Variance in microbiological standards for cured air-dried ready-to-eat (RTE) products for Listeria monocytogenes and Salmonella species testing.

The HACCP deficiencies noted above had been corrected. The Swiss meat inspection (BVET) officials explained changes in control procedures for inedible/condemned product or DOA carcasses. It was also stated that technical justification of the Swiss microbiological standards for RTE cured, air-dried product had been submitted to FSIS, International Policy Division (IPD) for equivalence determination.

Product prepared from beef of Swiss origin was not eligible for export to U.S. due to the presence in Switzerland of Bovine Spongiform Encephalopathy (BSE). Imported meat from U.S.-certified establishments in Brazil was used in preparation of U.S.-export product.

During calendar year 2000, Swiss establishments exported 6,138,277 lbs. of shelf-stable cureddried beef or pork (prosciutto) to the United States. There were no rejections at U.S. ports of entry.

PROTOCOL

The on-site audit was conducted in four parts. One part involved visits with Swiss meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection facilities preceding the on-site visits. The third part was conducted by on-site visits to establishments and to a dairy farm. The fourth was a visit to three laboratories testing chemical residues, *Escherichia coli* (*E. coli*), and *Salmonella* species: one official chemical and microbiological reference laboratory and two private accredited laboratories.

Program effectiveness determination focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation and operation of HACCP systems and the *E. coli*, *Salmonella* species and *Listeria monocytogenes* testing program, and (5) compliance enforcement controls, including the testing program for species identification. Switzerland's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the FSIS International Audit Staff Officer (hereinafter called "the Auditor"), evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The Auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/ adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

The Auditor also verified information provided by Switzerland in response to an FSIS questionnaire on Residue Control and Testing Programs, which included audits of records and discussions on laboratory testing, intra- and inter-agency legislation and regulatory authority regarding livestock health/husbandry; approval and use of veterinary and other regulated drugs; monitoring and control of feed additives and pre-mixes and residue withdrawal times; livestock identification; and compliance enforcement. This verification involved the following activities:

- A visit with *Intercantonal* [inter-State] Office for the Control of Medicine officials (approval and use of veterinary drugs),
- A visit with the Swiss Federal Research Station for Animal Production" officials (control of feed additives and pre-mix medicaments),
- A visit with BVET officials to discuss the national residue control program monitoring,
- Visits to Canton (State) Veterinary Offices (CVOs) in Zurich and Bern,
- A visit to a livestock farm, and
- A visit to the national Animal Tracing Database Corporation (TAD) Center in Bern (national database depository for livestock identification and disease tracing).

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in all six establishments. All six were evaluated as acceptable. Details of the audit findings, including compliance with the requirements for HACCP, SSOPs, and testing programs for *Salmonella* species and generic *Escherichia coli* (*E. coli*) are discussed later in this report.

As stated above, three major concerns had been identified during the last audit of the Swiss meat inspection system, conducted in March 1999, regarding HACCP implementation deficiencies, inadequate control of condemned materials, and variance in microbiological standards for cured air-dried ready-to-eat (RTE) products for *Listeria monocytogenes* and *Salmonella* species testing. During this new audit, the Auditor determined that these concerns had been addressed and corrected.

There was one concern with the HACCP programs; it will be discussed later in this report.

Entrance Meeting

On March 21, 2001, an entrance meeting was held at the BVET headquarters in Bern. It was attended by Dr. Peter Dollinger, Head of Division of Permits and Inspection; Dr. Silke Holznagel, Chief of Export Permits and Inspection; Drs. Christoph Jaggi and Pierre Heimann, Permits and Inspection Staff; and Mr. Hans-Jorg Heiz, Chief Chemist, National Residue Monitoring Program, and Dr. Hussain Magsi, International Audit Staff Officer, USDA, FSIS.. Topics of discussion included the following:

- 1. The audit itinerary,
- 2. SSOPs, HACCP programs, and testing programs for generic *E. coli* and *Salmonella* species testing,
- 3. Microbiological and chemical analysis and monitoring,
- 4. The national residue control program,
- 5. An audit of the control system for disposition of inedible/condemned or dead-on-arrival carcasses, and
- 6. Compliance enforcement.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. review of the Swiss inspection system in January 2000.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. requirements. The FSIS Auditor observed and evaluated the process.

The Auditor reviewed a selection of inspection system documents. This records review focused primarily on food safety hazards and included the following:

- Supervisory visits to establishments that were certified to export to the U.S.,
- Label approval records,
- Sampling and analyses for residues,
- Pathogen reduction and other food safety initiatives such as tuberculosis, cysticercosis, etc., and control inedible/condemned materials and DOA carcasses,
- Export product inspection and control, including export certificates,
- The national residue control program and monitoring results, and
- Compliance enforcement.

No concerns arose as a result the examination of these documents.

The Swiss inspection system had recently implemented a national livestock identification system and established a computerized data bank for over 1.5 million cattle, sheep and hogs.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Switzerland as eligible to export meat products to the United States were full-time or part-time BVET employees, receiving no remuneration from either the industry or the establishment personnel.

Establishment Audits

Six establishments were certified to export meat products to the United States at the time this audit was conducted; all six were visited for on-site audits. Swiss inspection system controls were in place to prevent, detect and control contamination and adulteration of products.

<u>Laboratory Audits</u>

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to the U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories; intra-laboratory quality assurance procedures, including sample handling; and methodology.

The BVET National Reference and Research Laboratory in Bern was audited on April 4, 2001. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

Switzerland's microbiological testing for Salmonella was being performed in contracted private laboratories. Two of these, the *Interlabor Laboratorien Belp AG* in Belp, and *UFAG Laboratories AG* in Sursee were audited on April 5, 2001 and April 6, 2001, respectively. The Auditor determined that the systems met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

- 1. The laboratories were accredited/approved by the government, accredited by a third party accrediting organization with oversight by the government, or a government contract laboratory.
- 2. The laboratories had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
- 3. Results of analyses were being reported to the government or simultaneously to the government and establishment.

Establishment Operations by Establishment Number

The following operations were being conducted in the six establishments:

Est. 121 – Swine and cattle slaughter and cutting

Est. 201 – Cured, dried beef and hams

Est. 205 – Cured, dried beef and hams

Est. 215 – Cured, dried beef and hams

Est. 293 – Cured, dried hams

Est. 324 – Cured, dried beef and hams

SANITATION CONTROLS

Based on the on-site audits of the establishments, Switzerland's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, handwashing facilities, sanitizers, separation of establishments, pest control, temperature control, lighting, operational and inspectors' work space, ventilation, over-product ceilings and equipment, product contact equipment, dry-storage areas, ante-mortem and welfare facilities, outside premises, personal dress and habits, equipment sanitizing, and product handling, storage, reconditioning, and transportation.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements.

ANIMAL DISEASE CONTROL

The Swiss inspection system had controls in place to ensure adequate animal identification, antemortem and post-mortem inspection procedures and dispositions, and restricted product control, and procedures for sanitary handling of returned and rework product.

With the exception of the presence of BSE in Switzerland, there were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

RESIDUE CONTROLS

Switzerland's National Residue Testing Plan for 2001 was being followed, and was on schedule. The Swiss inspection system had adequate controls in place to ensure compliance with sample handling and frequency, timely analysis, data reporting, tissue matrices, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, check sample programs, corrective actions, sampling and reporting procedures, and storage and use of chemicals. Methodologies were also acceptable.

Farm visit

The Auditor visited a private dairy farm and discussed husbandry and animal health controls with the farmer and one of the State Veterinary Officials. The observations and records review included inventories and authorized use of drugs and supplemental compounds/feed additives, and withdrawal time before slaughtering. No concerns arose as a result of this visit.

SLAUGHTER/PROCESSING CONTROLS

The Swiss inspection system had controls in place to ensure adequate ante-and post-mortem inspection procedures and dispositions; condemned and restricted product control, including disposition of dead, dying, diseased or disabled animals; humane handling and slaughter; returned and rework product; pre-boning trim; boneless meat inspection, ingredients identification, control of restricted ingredients, formulations, packaging materials, laboratory confirmation; label approvals; inspector monitoring; and processing equipment and records.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B)

In the HACCP plans in all six establishments, microbiological hazards had been identified as reasonably likely to occur at several process-control points, but no justification was provided for their not being considered Critical Control Points (CCPs). However, for each process, appropriate CCPs were identified and properly documented ensuring process control. Swiss officials stated that all establishments had committed to re-assess the HACCP plans and to correct the deficiencies. They gave assurances that appropriate actions would be taken in establishments that failed to meet the HACCP requirements.

Testing for Generic E. coli

Switzerland had adopted the FSIS regulatory requirements for generic *E. coli* testing with the exception of the following equivalent different requirements:

- 1. SAMPLE COLLECTOR. Government takes samples.
- There is a clearly written sampling plan with instruction for sample collection and processing that will be universally followed.
- The government has a means of ensuring that sample collection activities are appropriate.
- The government uses the test results to verify establishment slaughter, processing and dressing controls for fecal contamination.
- 2. LABORATORIES. Government laboratories.
- The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record keeping facilities.
- Results of analyses including all permanently recorded data and summaries are reported promptly to the establishment.

One establishment (Est. 121) was required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and was audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing program was found to meet the basic FSIS regulatory requirements.

ENFORCEMENT CONTROLS

Inspection System Controls

The Swiss inspection system controls were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. These included control of restricted product and inspection samples, shipment security, including

shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other counties for further processing. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for Salmonella Species

Switzerland had adopted the FSIS regulatory requirements for HACCP. *Salmonella* testing is the same with exception of the following equivalent measures:

- 1. LABORATORIES: Private laboratories analyze samples.
- The laboratories are contracted non-government laboratories that are all accredited by the government of Switzerland and must comply with SN EN 45 001: 1990 European standard. The laboratories are required to participate in competency testing to ensure laboratory analyses are properly performed and undergo periodic government audits.
- All accredited laboratories have a formal program which ensures that lab personnel are properly trained, that there are suitable facilities and equipment, that there is a written quality assurance program, and that there are adequate reporting and record keeping facilities.
- Test results are reported directly to inspection personnel.
- 2. SAMPLING TECHNIQUES: Time of collection of samples.
- Samples are taken at the end of the slaughter or production process.
- Samples are taken prior to the carcass being cut and/or packaged.
- 3. ANALYTICAL METHODS: Different methods.
- The laboratories use ISO 6579 to analyze for *Salmonella*. ISO 6579 is an internationally recognized method of analysis for detecting *Salmonella* and is closer to the FSIS method that the AOAC methods.

One establishment (Est. 121) was required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The Salmonella testing program was found to meet the basic FSIS regulatory requirements.

Species Verification Testing

At the time of this audit, Switzerland was exempt from the species verification requirement, having advised FSIS in writing that the following five conditions were being met:

- 1. Carcasses and products are transported between establishments in devices which are sealed with a tamper-detectable inspection seal by the Inspection Service at the originating establishment and broken by the Inspection Service at the receiving establishment.
- 2. Brands and sealing devices used by the Inspection Service to identify and seal product are kept under Inspection Service security.
- 3. Establishments are under continuous Inspection Service supervision while operating. No operations may take place without Inspection Service supervision.
- 4. Only one species of livestock or meat is allowed in the slaughter or processing areas at one time.
- 5. Product must be exported to the United States in a cargo container sealed by the Inspection Service.

During the audit, the auditor verified that these conditions continued to be met.

Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system to each establishment certified as eligible to export to the United States, not less frequently than one such visit per month, during any period when the establishment is engaged in producing product that could be used for exportation to the United States.

These reviews were conducted monthly by regional supervisors who contracted by BVET. The monthly audit reports were sent to the veterinary inspector and the headquarters in Bern and copies to the establishments.

BVET has the authority to withdraw approval for export. The regional BVET-designated supervisor or the Inspector-In-Charge provided the audit information to the headquarters, and can recommend withdrawal of an establishment's export permit for non-compliance with inspection system requirements. In case of non-compliance, the Inspector-In-Charge would make an initial report; this would be followed by the regional supervisor's audit report. These reports are sent to BVET in Bern for evaluation, with recommendations for export-permit suspension or re-instatement of export eligibility. BVET may conduct an on-site inspection of the establishment before reaching a final decision.

Enforcement Activities

The Internet site for the latest FSIS Quarterly Regulation and Enforcement Report was provided to BVET.

• Swiss legislation was in place to provide for enforcement actions pertaining to fines, product confiscation, and imprisonment, and there were provisions for actions to be taken if laws are violated. The Auditor reviewed the compliance enforcement case records in the State Veterinary offices in Zurich and Bern involving violations for exceeding tolerance levels of sulfonamides, incomplete documentation of livestock transportation, illegal slaughter (a goat farmer allowed insanitary slaughter on his premises sold the meat to customers; police were pursuing this case), and animal welfare violations with fines ranging from 50 to 4,000 Swiss francs.

Testing Ready-to-Eat Product for *Listeria monocytogenes* and *Salmonella* species

The establishments were routinely collecting ready-to-eat product samples for testing for *Salmonella* and *Listeria monocytogenes*. The samples were analyzed in State Public Health or accredited private laboratories. The BVET inspectors were monitoring these results. According to Swiss regulation (SR 817.051, June 26, 1995), in the event of a positive *Listeria* result, the next three lots are to be withheld and tested, and if the second sample is positive, additional samples are collected by official inspectors. Positive product may not be released for human consumption.

Exit Meeting

An exit meeting was conducted in Bern on April 9, 2001. The participants included Dr. Peter Dollinger, Head of Division of Permits and Inspection; Dr. Silke Holznagel, Chief of Export Permits and Inspection; Drs. Pierre Heimann, and Christoph Jaggi, Permits and Inspection Staff; Mr. Hans-Jorg Heize, Chief Chemist, National Residue Monitoring Program; and Dr. Hussain Magsi, International Audit staff Officer, FSIS.

Topics for discussion included the requirements of HACCP programs including hazards reasonably likely to occur, determination of critical control points, verification of monitoring of critical limits, and the reassessment and official verification of the HACCP implementation.

BVET officials stated that the issues had been discussed with the industry, and that the latter had committed to reassessing and modifying the HACCP plans within 30 to 60 days for BVET review. They assured the Auditor that appropriate actions would be taken if an establishment should fail to meet the HACCP requirements.

CONCLUSION

The Swiss inspection system and (except as noted above) establishment controls met FSIS requirements. The national residue control program augmented by the Canton (State) Veterinary Office's residue control and compliance enforcement program is effective.

(Signed) Dr. Hussain Magsi, DVM, MS Dr. Hussain Magsi, DVM, MS International Audit Staff Officer

Attachments

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instruments for generic *E. coli* testing
- D. Data collection instruments for Salmonella testing
- E. Laboratory Audit Forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the final report

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

- 1. The establishment has a written SSOP program.
- 2. The procedure addresses pre-operational sanitation.
- 3. The procedure addresses operational sanitation.
- 4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
- 5. The procedure indicates the frequency of the tasks.
- 6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
- 7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
- 8. The procedure is dated and signed by the person with overall on-site authority.

The results of the establishments visited on-site were evaluated as follows:

| Est. No. | Written program addressed | 2. Pre-op sanitation addressed | 3. Operational sanitation addressed | 4. Contact surfaces addressed | 5. Frequency addressed | 6. Responsible individual identified | 7. Document- ation done daily | 8. Dated and signed |
|-------------|---------------------------|--------------------------------------|-------------------------------------|-------------------------------------|------------------------|--------------------------------------|-------------------------------------|---------------------|
| 121 | √ | √ | V | V | V | V | V | V |
| 201 | | V | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ |
| 205 | $\sqrt{}$ | V | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ |
| 215 | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ |
| 293 | V | V | V | V | V | V | V | V |
| 324 | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ |

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. The establishment has a flow chart that describes the process steps and product flow.
- 2. The establishment had conducted a hazard analysis.
- 3. The analysis includes food safety hazards likely to occur.
- 4. The analysis includes the intended use of or the consumers of the finished product(s).
- 5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
- 6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
- 7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
- 8. The plan describes corrective actions taken when a critical limit is exceeded.
- 9. The HACCP plan was validated using multiple monitoring results.
- 10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
- 11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
- 12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

| Est. | 1.Flow | 2.Hazar | 3. All | 4. Use & | 5. Plan | 6. CCPs | 7.Monit. | 8. Correc- | 9. Plan | 10. | 11. Ade- | 12. |
|------|---------|--------------|--------------|--------------|--------------|----------|-----------|------------|--------------|-----------|--------------|-----------|
| No | diagram | d | hazards | users | for | for all | critical | tive | valida- | Adeq. | quacy of | Dated |
| | | analysi | identif. | included. | each | hazards | limits, | actions | ted | Verific. | docume- | and |
| | | s done | | | hazard | analyzed | and freq. | described | | Proc. | entation. | Signed |
| | | | | | | | Specified | | | | | |
| 121 | | \checkmark | \checkmark | \checkmark | $\sqrt{}$ | No | $\sqrt{}$ | $\sqrt{}$ | \checkmark | $\sqrt{}$ | \checkmark | |
| 201 | | | \checkmark | | \checkmark | No | | $\sqrt{}$ | | | | $\sqrt{}$ |
| 205 | | | $\sqrt{}$ | | $\sqrt{}$ | No | | | | | | $\sqrt{}$ |
| 215 | | | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | No | | | | | $\sqrt{}$ | $\sqrt{}$ |
| 293 | V | V | V | V | $\sqrt{}$ | No | V | V | | V | V | |
| 324 | V | V | V | V | $\sqrt{}$ | No | V | V | | V | V | $\sqrt{}$ |

^{6.} Microbiological hazards likely to occur were identified in most process control steps but not documented as critical control points, although no justification was provided for their not being considered CCPs.

Data collection instruments for E. coli testing

All slaughter establishments were evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the equivalent criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. The establishment has a written procedure for testing for generic *E. coli*.
- 2. The procedure designates the employee(s) responsible to collect the samples.
- 3. The procedure designates the establishment location for sample collecting.
- 4. The sample collection is done on the predominant species being slaughtered.
- 5. The sampling is done at the frequency specified in the procedure.
- 6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
- 7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
- 8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
- 9. The results of the tests are being recorded on a process control chart showing the most recent test results.
- 10. The test results are being maintained for at least 12 months.

The results of these evaluations were as follows:

| Est. | 1. | Sample | 3.Sampling | 4.Predomi- | 5.Sampling | 6.Proper | 7.Sampling | 8. Using | Chart or | Results |
|------|-----------|--------------------------|------------|------------|-------------|-----------|------------|----------|----------------------------|---------------------------|
| No. | Written | collector | location | nant spp. | at required | site or | is random | AOAC | graph of | are kept at |
| | procedure | designated | given | sampled | frequency | method | | method | results | least 1 yr |
| 121 | | | $\sqrt{}$ | $\sqrt{}$ | | $\sqrt{}$ | $\sqrt{}$ | | | $\sqrt{}$ |

Data Collection instruments for Salmonella spp. Testing

All slaughter establishments were evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* species testing were met, according to the equivalent criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. Salmonella testing is being done in this establishment.
- 2. Carcasses are being sampled.
- 3. Ground product is being sampled.
- 4. The samples are being taken randomly.
- 5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
- 6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

| Est. No. | 1. Testing as required | 2. Carcasses are sampled | 3. Ground product is sampled | 4. Samples are taken randomly | 5. Proper site and/or proper production | 7. Violative Est. stop operations |
|-------------|------------------------|--------------------------|------------------------------|-------------------------------|---|-----------------------------------|
| 121 | V | V | 1 | V | √ | N/A |

TIII E Y

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE 4-06-01 NAME OF FOREIGN LABORATORY

UFAG-Laboratorein AG

FOREIGN GOV'T AGENCY
Meat Inspection and Veterinary service

CITY & COUNTRY
Sursee, Switzerland

ADDRESS OF LABORATORY
Sursee, Switzerland

NAME OF REVIEWER Dr. H. Magsi

NAME OF FOREIGN OFFICIAL

Dr. S. Holznagel

| | | | 2. S. Holango | | | | | | | | | | | | |
|---------------------------------|------------------------------|--------|---------------|--|-----------|---------|-----|-------------|------|------|------------|---------|---|----------|--|
| | Residue Code/Nan | ne | > | 100 | 111 | 200 | 203 | 300 | Ecol | Sal | List | | | | |
| | REVIEW ITEMS | ITEM A | 7 | | | | | | | | | | | | |
| | Sample Handling | 01 | | A | A | A | ٨ | A | ٨ | ٨ | A | | ļ | | |
| OURES | Sampling Frequency | 02 | CODE | ٨ | A | ٨ | ٨ | A | A | Α | A | | | | |
| PROCE | Timely Analyses | 03 | | A | A | A | A | A | ٨ | ٨ | A - | | | | |
| SAMPLING PROCEDURES | Compositing Procedure | 04 | EVALUATION | 0 | o | o | o | 0 | 0 | o | o | | | | |
| SAM | Interpret Comp Data | 05 | <u></u> | 0 | 0 | o | o | 0 | 0 | o | o | | | | |
| | Data Reporting | 06 | | A | A | A | A | A_ | ٨ | ٨ | A | | | | |
| | Acceptable Method | 07 | C00E | A | A | ٨ | A | A | ٨ | ٨ | ٨ | | | | |
| ANALYTICAL PROCEDURES | Correct Tissue(s) | 08 | NO NO | A | A | ٨ | A | A | A | ٨ | ٨ | | | | |
| ANAL | Equipment Operation | 09 | EVALUATION | A | A | ٨ | A | A | A | A | | | | | |
| | Instrument Printouts | 10 | 2 | A ES | ٨ | 0 | A | Α | ٨ | ^ | 0 | | | | |
| | Minimum Detection Levels | 11 | | ٨ | A | A | A | A | 0 | 0 | 0 | | | | |
| ACE. | Recovery Frequency | 12 |] " | A | ٨ | A | A | A | 0 | o | 0 | | | | |
| URAI | Percent Recovery | 13 | - JOS | ٨ | A | A | A | A | 0 | 0 | 0 | | | | |
| QUALITY ASSURANCE PROCEDURES | Check Sample Frequency | 14 | EVALUATION | A | A | A | A | A | A | A | A | | | <u> </u> | |
| Ę | All analyst w/Check Samples | 15 | ALU, | A | A | A | A | A | A | A | A | | | | |
| ð | Corrective Actions | 16 | 2 | A | A | A | A | A | A | A | ٨ | | | | |
| | International Check Samples | 17 | | 0 | o | 0 | 0 | ٨ | A | A | A | | | <u> </u> | |
| REVIEW PROCEDURES | Corrected Prior Deficiencies | 18 | EVAL. CODE | 0 | 0 | 0 | 0 | 0 | 0 | o | 0 | | | | |
| OTHER | | 19 | CODE | | | | | | | | | | | | |
| OT! | | 20 | FVAL | | | | | | | | | | | | |
| SIGNA | TURE OF REVIEWER | · | | ــــــــــــــــــــــــــــــــــــــ | <u></u> . | | | | 1 | DATE | | | | | |

E-2

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE 4-04-01 NAME OF FOREIGN LABORATORY

BVET National Reference and Reserach Laboratory

FOREIGN GOV'T AGENCY

Meat Inspection and Veterinary service

CITY & COUNTRY Bern, Switzerland ADDRESS OF LABORATORY Bern, Switzerland

NAME OF REVIEWER

Dr. H. Magsi

NAME OF FOREIGN OFFICIAL

Dr. S. Holznagel

| | | | | · | | | | | | | | | | | |
|---------------------------------|------------------------------|--------|-----------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|--|
| | Residue Code/Nan | ne 🕨 | > | 100 | 111 | 200 | 203 | 300 | 400 | 500 | 800 | 923 | Sal | Ecol | List |
| | REVIEW ITEMS | ITEM # | | | | | | | | | | | | | |
| | Sample Handling | 01 | | A | | ٨ | A | A | A | A | A | A | A_ | ٨ | ٨ |
| DURES | Sampling Frequency | 02 | ODE | A | A | A | A | ٨ | A | A | A | A | A | A | ٨ |
| PROCE | Timely Analyses | 03 | TION C | A | A | ٨ | A | A | A | A | A | A | ٨ | ^ | A |
| SAMPLING PROCEDURES | Compositing Procedure | 04 | EVALUATION CODE | 0 | o | o | 0 | 0 | 0 | o | o | o | 0 | o | o |
| SAN | Interpret Comp Data | 05 | ۳ | 0 | o | 0 | o | o | o | o | o | o | 0 | o | o |
| | Data Reporting | 06 | | A | ٨ | A | ٨ | ٨ | ٨ | Α_ | A | A | A | Ą | A |
| | Acceptable Method | 07 | E E | A | A | A | A | A | A | A | A | A | ٨ | ٨ | ٨ |
| ANALYTICAL PROCEDURES | Correct Tissue(s) | 08 | EVALUATION CODE | A | A | ٨ | A | ٨ | A | A | A | A | A | A | A |
| ANAL | Equipment Operation | 09 | ALUAT | A | A | ٨ | A | A | A | A | A | A | A | A | A |
| | Instrument Printouts | 10 | 2 | A | A | 0 | A | ٨ | A | A | A | ٨ | o | o | o |
| | Minimum Detection Levels | 11 | | A | A | A | A | A | A | A | A | A | 0 | O | o |
| 4CE | Recovery Frequency | 12 | ٦ | A | A | A | A | A | A | A | A | A | 0 | 0 | 0 |
| QUALITY ASSURANCE PROCEDURES | Percent Recovery | 13 | Z CODE | A | A | A | A | A | ^ | ٨ | A | A | 0 | o | 0 |
| r ASS | Check Sample Frequency | 14 | EVALUATION | A | A | A | A | A | A | A | A | A | A | ٨ | A |
| ALIT | All analyst w/Check Samples | 15 | 1§ | A_ | A | A | A | A | A | A | A | A | A | ٨ | A |
| 8 | Corrective Actions | 16 |] 🖫 | A | A | A | A | A | A | A | A | A | A | ٨ | A |
| | International Check Samples | 17 | | 0 | 0 | 0 | 0 | A | A | A | A | A | 0 | 0 | A |
| REVIEW PROCEDURES | Corrected Prior Deficiencies | 18 | EVAL. CODE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6 |
| OTHER REVIEW | | 19 | CODE | | | | | | | | | | | | |
| I = | | 1 | EVAL. | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | t | ı |

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS 4-05-01

NAME OF FOREIGN LABORATORY

Interlabor Laboratorein Belp AG

FOREIGN COUNTRY LABORATORY REVIEW

CITY & COUNTRY Belp, Switzerland ADDRESS OF LABORATORY Belp, Switzerland

NAME OF REVIEWER Dr. H. Magsi

FOREIGN GOV'T AGENCY

Meat Inspection and Veterinary service

NAME OF FOREIGN OFFICIAL

Dr. S. Holznagel

| | Residue Code/Nan | 30 | - | 100 | 111 | 200 | 203 | 300 | Ecol | Sal | List | | <u> </u> | |
|---------------------------------|------------------------------|--------|-----------------|-----|---------|----------|-------------|-----|--------------|------|------|---|-------------|------------------|
| | REVIEW ITEMS | ITEM # | | 100 | ••• | 200 | 203 | 300 | 12001 | - | List | | | |
| | Sample Handling | 01 | | A | A | ٨ | A | ٨ | A | A | A | | <u>.</u> | |
| OURES | Sampling Frequency | 02 | OE SOE | A | A | ٨ | A | ^ | A | A | A | | | |
| SAMPLING PROCEDURES | Timely Analyses | 03 | EVALUATION CODE | A | A | A | A | ٨ | A | A | A | | | |
| APLING | Compositing Procedure | 04 | VALUA | 0 | 0 | 0 | 0 | o | 0 | o | o | | | |
| SAN | Interpret Comp Data | 05 | 3 | 0 | 0 | 0 | o | 0 | О | o | o | | | |
| : | Data Reporting | 06 | | A | A | A | A | A | A | ٨ | Α | | | |
| | Acceptable Method | 07 | CODE | A | A | A | A | ٨ | A | A | ٨ | | | |
| TICAL | Correct Tissue(s) | 08 | ION C | A | A | A | A | ٨ | A_ | ٨ | A | | | |
| ANALYTICAL PROCEDURES | Equipment Operation | 09 | EVALUATION | A | A | A | ٨ | A | A | ٨ | A | | | |
| | Instrument Printouts | 10 | EVALL | A | 0 | A | A | A | ٨ | 0 | | | | |
| , | Minimum Detection Levels | 11 | 1 A | A | A | A | A | ٨ | 0 | 0 | 0 | | | |
| S | Recovery Frequency | 12 | ٦ | A | A | ٨ | ٨ | ٨ | 0 | o | 0 | | | |
| URAN | Percent Recovery | 13 | CODE | A | A | A | A | A | o | 0 | 0 | | | |
| ASS | Check Sample Frequency | 14 | Ę | A | A | A | A | A | A | A | ٨ | | | |
| QUALITY ASSURANCE PROCEDURES | All analyst w/Check Samples | 15 | EVALUATION | A | A | ٨ | A | A | A | A | A | | | |
| ð | Corrective Actions | 16 | 2 | A | ٨ | ٨ | A | A | A | A | A | | | |
| | International Check Samples | 17 | | 0 | 0 | 0 | 0 | A | A | A | ٨ | | | |
| REVIEW PROCEDURES | Corrected Prior Deficiencies | 18 | EVAL. CODE | ٥ | o | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| OTHER REVIEW | | 19 | CODE | | | | | | | | | | | |
| OTP | | 20 | EVAL. | | | | | | | | | | | |
| SIGNAT | TURE OF REVIEWER | L | ل | 1 | | <u> </u> | | | | DATE | | L | | |

| U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS | REVIE | W DATE | ESTABLISHMENT NO. AND NAM | E | | CITY Klus | | |
|--|-----------------|-----------|--------------------------------|-----------------|-------------------------|-------------------|--------------------|--|
| FOREIGN PLANT REVIEW FORM | 4/2 | 2/2001 | 121 - Gehrig AG | | | COUNTRY | | |
| NAME OF REVIEWER | NAM | OE EODE | IGN OFFICIAL | | EVALUATION | Switzerland | | |
| Dr. H. Magsi | | S. Holzna | | | | eptable/ | eptable | |
| CODES (Give an appropriate code for each r A = Acceptable M = Margina | | | below) U = Unacceptable | N = | - Not Reviewed | O = Does not ap | oply | |
| 1. CONTAMINATION CONTROL | | Cross c | ontamination prevention | 28 A | Formulations | | 55 A | |
| (a) BASIC ESTABLISHMENT FACILITIES | | Equipm | ent Sanitizing | 29 A | Packaging materi | als | 56 A | |
| Water potability records | 01 A | Product | handling and storage | 30 A | Laboratory confirmation | | | |
| Chlorination procedures | 02 A | Product | reconditioning | 31 A | Label approvals | | 58 A | |
| Back siphonage prevention | 03 A | Product | transportation | 32 A | Special label claims | | | |
| Hand washing facilities | 04 A | (d) ES | TABLISHMENT SANITATION PROGRAI | M | Inspector monitor | ring | 59 O 60 A | |
| Sanitizers | 05 A | Effectiv | e maintenance program | 33 A | Processing sched | ules | 61 O | |
| Establishments separation | 06 A | Preoper | ational sanitation | 34 A | Processing equip | ment | 62 A | |
| Pestno evidence | 07 A | Operation | onal sanitation | 35 A | Processing record | ls | 63 A | |
| Pest control program | 08 A | Waste | disposal | 36 A | Empty can inspec | ction | 64 O | |
| Pest control monitoring | 09 A | | 2. DISEASE CONTROL | | Filling procedures | | 65 O | |
| Temperature control | 10 A | Animal | identification | 37 A | Container closure | exam | 66 O | |
| Lighting | 11 _A | Antemo | ortem inspec. procedures | 38 A | Interim container | handling | 67 O | |
| Operations work space | 12 A | Antemo | ortem dispositions | 39 A | Post-processing h | nandling | 68 O | |
| Inspector work space | 13 A | Human | e Slaughter | 40 A | Incubation proced | dures | 69 O | |
| Ventilation | 14 A | Postmo | rtem inspec. procedures | 41 A | Process. defect a | ctions plant | 70 A | |
| Facilities approval | 15 A | Postmo | rtem dispositions | 42 A | Processing contro | ol inspection | 71 A | |
| Equipment approval | 16 A | Conden | nned product control | 43 A | 5. COMPLIANCE/EC | CON. FRAUD CONTRO | _ | |
| (b) CONDITION OF FACILITIES EQUIPMENT | r | Restrict | ed product control | 44 _A | Export product id | entification | 72 A | |
| Over-product ceilings | 17 A | Returne | ed and rework product | 45 A | Inspector verifica | tion | 73 A | |
| Over-product equipment | 18 A | | 3. RESIDUE CONTROL | | Export certificate | S | 74 A | |
| Product contact equipment | 19 A | Residue | program compliance | 46 A | Single standard | | 75 A | |
| Other product areas (inside) | 20 A | Samplin | ng procedures | 47 A | Inspection super | rision | 76 A | |
| Dry storage areas | 21 A | Residue | reporting procedures | 48 A | Control of securit | ty items | 77 A | |
| Antemortem facilities | 22 A | Approv | al of chemicals, etc. | 49 A | Shipment securit | Y | 78 A | |
| Welfare facilities | 23 A | Storage | and use of chemicals | 50 A | Species verificati | on | 79 A | |
| Outside premises | 24 A | 4 | I. PROCESSED PRODUCT CONTROL | | "Equal to" status | | 80 A | |
| (c) PRODUCT PROTECTION & HANDLING | | Pre-bor | ning trim | 51 A | Imports | | 81 A | |
| Personal dress and habits | 25 A | Boneles | ss meat reinspection | 52 A | SSOPs | | 82 A | |
| Personal hygiene practices | 26 A | Ingredi | ents identification | 53 A | НАССР | | 83 M | |
| Sanitary dressing procedures | 27 A | Control | of restricted ingredients | 54 A | | | | |

| | | | | | | <u> </u> | • |
|---|----------------|-----------|-------------------------------|-----------------|---------------------|---------------------------|----------------|
| U.S. DEPARTMENT OF AGRICULTURE OOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS | | W DATE | ESTABLISHMENT NO. AND NAM | Œ | | CITY Trin | |
| FOREIGN PLANT REVIEW FORM | 3/ | 27/01 | 201 - Gurtner AG | | | COUNTRY Switzerland | |
| NAME OF REVIEWER | NAM | OF FORE | IGN OFFICIAL | | EVALUATION | Switzerland | |
| Dr. H. Magsi | Dr. | S. Holzna | igel | | ſŢ, ∏Acc | ceptable/ review Unacc | eptable |
| CODES (Give an appropriate code for each r A = Acceptable | | | below) U = Unacceptable | N : | = Not Reviewed | O = Does not a | pply |
| 1. CONTAMINATION CONTROL | | Cross c | ontamination prevention | 28 A | Formulations | W | 55 A |
| (a) BASIC ESTABLISHMENT FACILITIES | | Equipm | ent Sanitizing | 29 A | Packaging materi | als | 56 A |
| Water potability records | 01 A | Product | handling and storage | 30 A | Laboratory confirm | mation | 57 A |
| Chlorination procedures | 02 A | Product | reconditioning | 31 A | Label approvals | | 58 A |
| Back siphonage prevention | 03 A | Product | transportation | 32 A | Special label clair | ns | 59 O |
| Hand washing facilities | 04 A | (d) ES | TABLISHMENT SANITATION PROGRA | | Inspector monitor | ring | 60 A |
| Sanitizers | 05 A | Effectiv | e maintenance program | 33 A | Processing sched | ules | 61 O |
| Establishments separation | 06 A | Preoper | ational sanitation | 34 A | Processing equip | ment | 62 A |
| Pestno evidence | 07 A | Operati | onal sanitation | 35 A | Processing record | is | 63 A |
| Pest control program | 08 A | Waste | disposal | 36 A | Empty can inspec | ction | 64 O |
| Pest control monitoring | 09 A | | 2. DISEASE CONTROL | | Filling procedures | ; | 65 O |
| Temperature control | 10 A | Animal | identification | 37 O | Container closure | exam | 66 O |
| Lighting | 11 A | Antemo | ortem inspec. procedures | 38 O | Interim container | handling | 67 O |
| Operations work space | 12 A | Antemo | ortem dispositions | 39 O | Post-processing h | nandling | 68 O |
| Inspector work space | 13 A | Human | e Slaughter | 40 | Incubation proced | dures | 69 A |
| Ventilation | 14 A | Postmo | rtem inspec. procedures | 41 O | Process. defect a | ections plant | 70 A |
| Facilities approval | 15 A | Postmo | rtem dispositions | 42 O | Processing contro | ol inspection | 71 A |
| Equipment approval | 16 A | Conden | nned product control | 43 A | 5. COMPLIANCE/E | CON. FRAUD CONTRO |)L |
| (b) CONDITION OF FACILITIES EQUIPMENT | Γ | Restrict | ed product control | 40 | Export product id | entification | 72 A |
| Over-product ceilings | 17 A | Returne | ed and rework product | 45 O | Inspector verifica | tion | 73 A |
| Over-product equipment | 18 A | | 3. RESIDUE CONTROL | | Export certificate | S | 74 A |
| Product contact equipment | 19 A | Residue | program compliance | 46 O | Single standard | | 75 A |
| Other product areas (inside) | 20 A | Samplin | ng procedures | 47 ₀ | Inspection superv | rision | 76 A |
| Dry storage areas | 21 A | Residue | reporting procedures | 48 O | Control of securit | ty items | 77 A |
| Antemortem facilities | 22 O | Approv | al of chemicals, etc. | 49 A | Shipment securit | Y | 78 A |
| Welfare facilities | 23 A | Storage | and use of chemicals | 50 A | Species verificati | on | 79 A |
| Outside premises | 24 A | 4 | . PROCESSED PRODUCT CONTROL | ** | "Equal to" status | | 80 A |
| (c) PRODUCT PROTECTION & HANDLING | | Pre-bor | ing trim | 51 A | Imports | | 81 A |
| Personal dress and habits | 25 A | Boneles | ss meat reinspection | 52 A | SSOPs | | 82 A |
| Personal hygiene practices | 26 A | Ingredi | ents identification | 53 A | НАССР | | 83 M |
| Sanitary dressing procedures | 27 O | Control | of restricted ingredients | 54 A | | | |

| REVIE | W DATE | ESTABLISHMENT NO. AND NAMI | Ē | CITY | |
|----------------|--|--|--|--|---|
| 3/ | 28/01 | 205 - Albert Spiess | | Frauenkirch | |
| 31. | <i>2</i> 0/01 | 203 - Moore opiess | | COUNTRY Switzerland | |
| | | | | EVALUATION | |
| | | <u> </u> | | X Acceptable Acceptable/ Re-review Unacc | eptable |
| | | U = Unacceptable | N = | Not Reviewed O = Does not a | pply |
| | Cross c | ontamination prevention | 28 A | Formulations | 55 A |
| | Equipm | ent Sanitizing | 29 A | Packaging materials | 56 A |
| 01 A | Product | handling and storage | 30 A | Laboratory confirmation | 57 A |
| 02 A | Product | reconditioning | 31 A | Label approvals | 58 A |
| 03 A | Product | transportation | 32 A | Special label claims | 59 O |
| 04 A | (d) E | STABLISHMENT SANITATION PROGRAM | VI | Inspector monitoring | 60 A |
| 05 A | Effectiv | re maintenance program | 33 A | Processing schedules | 61 O |
| 06 A | Preoper | ational sanitation | 34 A | Processing equipment | 62 A |
| 07 A | Operati | onal sanitation | 35 A | Processing records | 63 O |
| 08 A | Waste | disposal | 36 A | Empty can inspection | 64 O |
| 09 A | | 2. DISEASE CONTROL | | Filling procedures | 65 O |
| 10 A | Animal | identification | | Container closure exam | 66 O |
| 11 A | Antemo | ortem inspec. procedures | 38 O | Interim container handling | 67 O |
| 12 A | Antemo | ortem dispositions | 39 O | Post-processing handling | 68 O |
| 13 A | Human | e Slaughter | 40 O | Incubation procedures | 69 O |
| 14 A | Postmo | rtem inspec. procedures | 41 ₀ | Process. defect actions plant | 70 A |
| 15 A | Postmo | ortem dispositions | 42 O | Processing control inspection | 71 A |
| 16 A | Conder | nned product control | | 5. COMPLIANCE/ECON, FRAUD CONTR | OL . |
| τ | Restric | ted product control | 40 | Export product identification | 72 A |
| 17 A | Return | ed and rework product | 45 O | Inspector verification | 73 A |
| 18 A | | 3. RESIDUE CONTROL | | Export certificates | 74 A |
| 19 A | Residu | e program compliance | 46 O | Single standard | 75 A |
| 20 A | Sampli | ng procedures | 47 O | Inspection supervision | 76 A |
| 21 A | Residu | e reporting procedures | 48 O | Control of security items | 77 A |
| | Approv | val of chemicals, etc. | 49 A | Shipment security | 78 A |
| 23 A | Storag | e and use of chemicals | 50 A | Species verification | 79 A |
| 24 A | | 4. PROCESSED PRODUCT CONTROL | | "Equal to" status | 80 A |
| 3 | Pre-bo | ning trim | 51 A | Imports | 81 A |
| 25 A | Bonele | ss meat reinspection | 52 A | SSOPs | 82 A |
| 26 A | Ingredi | ents identification | 53 A | HACCP | 83 M |
| 27 O | Contro | l of restricted ingredients | 54 A | | |
| | 3/1 NAME Dr. eview ally Acc 01 A 02 A 03 A 04 A 05 A 06 A 07 A 08 A 11 | Dr. S. Holzna eview item listed ally Acceptable Cross c Equipme 1 A Product 1 A Product 1 A Product 1 A Preoper 1 A Operati 1 A Antemo 1 A Antemo 1 A Antemo 1 A Restrict 1 A Residue 2 A Residue 3 A Residue 4 A Residue 4 A Residue 2 A Residue 2 A Residue 3 A Residue 4 A R | NAME OF FOREIGN OFFICIAL Dr. S. Holznagel eview item listed below) ally Acceptable Cross contamination prevention Equipment Sanitizing O1A Product handling and storage O2A Product transportation O4A (d) ESTABLISHMENT SANITATION PROGRAM O5A Effective maintenance program O6A Preoperational sanitation O7A Operational sanitation O8A A L. DISEASE CONTROL O8A Antemortem dispositions O1A Antemortem dispositions | NAME OF FOREIGN OFFICIAL Dr. S. Holznagel eview item listed below) alty Acceptable Cross contamination prevention Equipment Sanitizing Cross contamination prevention Equipment Sanitizing Product handling and storage A Product reconditioning A Product transportation Cross contamination prevention A Product transportation A A A A Cross contamination prevention A Product transportation Cross contamination prevention Cross contamination prevention Cross contamination C | NAME OF FOREIGN OFFICIAL Dr. S. Holyagel Secondaria Secondaria |

| U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS | REVIE | W DATE | ESTABLISHMENT NO. AND NAM | | CITY Churwalden | | | |
|--|-----------------|-----------|--------------------------------|-----------------|----------------------------|---------------------------|---------|--|
| FOREIGN PLANT REVIEW FORM | 3/2 | 6/2001 | 215 - Fleischtrocknerei Churw | /alden | AG | COUNTRY | | |
| NAME OF REVIEWER | NAM | OF FORE | IGN OFFICIAL | - | EVALUATION: | Switzerland | | |
| Dr. H. Magsi | | S. Holzna | | | EVALUATION Acceptable Re- | ceptable/ review Unacc | eptable | |
| CODES (Give an appropriate code for each r A = Acceptable M = Margina | | | below) U = Unacceptable | N = | = Not Reviewed | O = Does not ap | | |
| 1. CONTAMINATION CONTROL | | Cross c | ontamination prevention | 28 A | Formulations | | 55 | |
| (a) BASIC ESTABLISHMENT FACILITIES | | Equipme | ent Sanitizing | 29 A | Packaging materi | als | 56 A | |
| Water potability records | 01 A | Product | handling and storage | 30 A | Laboratory confir | mation | 57 A | |
| Chlorination procedures | 02 A | Product | reconditioning | 31 A | Label approvals | | 58 A | |
| Back siphonage prevention | 03 A | Product | transportation | 32 A | Special label claims | | | |
| Hand washing facilities | 04 A | (d) ES | TABLISHMENT SANITATION PROGRAM | Я | Inspector monitor | ring | 60 A | |
| Sanitizers | 05 A | Effectiv | e maintenance program | 33 A | Processing sched | ules | 61 O | |
| Establishments separation | 06 A | Preoper | ational sanitation | 34 A | Processing equip | ment | 62 A | |
| Pestno evidence | 07 A | Operati | onal sanitation | 35 A | Processing record | is | 63 A | |
| Pest control program | 08 A | Waste | disposal | 36 A | Empty can inspec | ction | 64 O | |
| Pest control monitoring | 09 A | | 2. DISEASE CONTROL | | Filling procedures | • | 65 O | |
| Temperature control | 10 A | Animal | identification | 37 O | Container closure | exam | 66 O | |
| Lighting | 11 _A | Antemo | ortem inspec. procedures | 38 O | Interim container | handling | 67 O | |
| Operations work space | 12 A | Antemo | ortem dispositions | 39 O | Post-processing I | nandling | 68 O | |
| Inspector work space | 13 A | Human | e Slaughter | 40 O | Incubation proced | dures | 69 O | |
| Ventilation | 14 A | Postmo | rtem inspec. procedures | 41 ₀ | Process. defect a | ctions plant | 70 A | |
| Facilities approval | 15 A | Postmo | rtem dispositions | 42 O | Processing contro | ol inspection | 71 A | |
| Equipment approval | 16 A | Conden | nned product control | 43 A | 5. COMPLIANCE/E | CON. FRAUD CONTRO | X. | |
| (b) CONDITION OF FACILITIES EQUIPMENT | | Restrict | ted product control | 40 | Export product id | lentification | 72 A | |
| Over-product ceilings | 17 A | Returne | ed and rework product | 45 O | Inspector verifica | ition | 73 A | |
| Over-product equipment | 18 A | | 3. RESIDUE CONTROL | | Export certificate | s | 74 A | |
| Product contact equipment | 19 A | Residue | program compliance | 46 O | Single standard | | 76 A | |
| Other product areas (inside) | 20 A | Samplin | ng procedures | 47 O | Inspection super | vision | 76 A | |
| Dry storage areas | 21 A | Residue | e reporting procedures | 48 O | Control of securi | ty items | 77 A | |
| Antemortem facilities | 22 O | Approv | al of chemicals, etc. | 49 A | Shipment securit | Υ | 78 A | |
| Welfare facilities | 23 A | Storage | e and use of chemicals | 50 A | Species verificati | ion | 79 A | |
| Outside premises | 24 A | 4 | I. PROCESSED PRODUCT CONTROL | | "Equal to" status | | 80 A | |
| (c) PRODUCT PROTECTION & HANDLING | | Pre-bor | ning trim | 51 A | Imports | | 81 A | |
| Personal dress and habits | 25 A | Bonele | ss meat reinspection | 52 A | SSOPs | | 82 A | |
| Personal hygiene practices | 26 A | Ingredi | ents identification | 53 A | НАССР | | 83 M | |
| Sanitary dressing procedures | 27 O | Contro | of restricted ingredients | 54 A | | | | |

| U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS | | W DATE | 203 Salumi San Dadro SA Drodor SA | | | Stabio T | |
|--|---|---|-----------------------------------|--------------------|---------------------------------------|------------------------|----------------|
| FOREIGN PLANT REVIEW FORM | 3/2 | 9/2001 293 Salumi San Pedro SA, Prodor SA | | | SA | COUNTRY Switzerland | |
| NAME OF REVIEWER Dr. H. Magsi | NAME OF FOREIGN OFFICIAL Dr. S. Holznagel | | | | EVALUATION Acceptable Re- | ceptable/ Unacc | eptable |
| CODES (Give an appropriate code for each of A = Acceptable M = Margin | | | below) U = Unacceptable | N = | = Not Reviewed | O = Does not a | pply |
| 1. CONTAMINATION CONTROL | | Cross contamination prevention | | 28 A | Formulations | | 55 A |
| (a) BASIC ESTABLISHMENT FACILITIES | | Equipm | ent Sanitizing | 29 A | Packaging materi | ials | 56 A |
| Water potability records | 01 A | Product | handling and storage | 30 A | Laboratory confir | mation | 57 A |
| Chlorination procedures | 02 A | Product | reconditioning | 31 A | Label approvals | | 58 A |
| Back siphonage prevention | 03 A | Product | transportation | 32 A | Special label clair | ms | 59 A |
| Hand washing facilities | 04 A | (d) ESTABLISHMENT SANITATION PROGRAM | | | Inspector monitoring 60 A | | |
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F-5a

ATIOCHMENT



Bundesamt für Veterinärwesen Office vétérinaire fédéral Ufficio federale di veterinaria Uffizi federal veterinar

Your ref.

Letter dated Oct 12, 2001

Our ref. Date

SH-201,403 Dec 18, 2001

40to

Fax: 001 202 690-7896

FSIS

Office of the Director International Policy Division Room 4434 South Building

14th Street and independence Avenue, SW

Washington DC 20250-3700

On-site audit of Switzerland's meat Inspection system/ Draft Final of the Audit Report

Dear Mrs. Stratmoen

Thank you for the draft of the final audit-report, which we received October 22, 2001.

We would like to take the opportunity to address two points, which may have been misunderstood:

1. Testing for Generic E.coli, Page 7:

This is a program, which the approved establishment is obliged to run. The inspector verifies if the conditions are met with regard to sampling procedures, analytical methods, corrective actions and documentation. The lab has a contract with the establishment.

2. Species Verification Testing, page 9:

We would like to clarify some details:

The products eligible for exporting to the United States are pork (harn) and beef (air-dried beef) products. Ham is normally from Switzerland, establishment no. 121 is approved for slaughter and cutting. The carcasses or the cuts are marked with the official health mark. Depending on the size of the cuts they are transported hanging like carcasses or in sealed containers. The meat is accompanied by a health certificate signed by the official inspector. In the receiving processing plant the meat is checked by plant personal 100%, the inspector monitors the own-checks, additionally he himself checks incoming meat randomly.

Beef originates from South American sources (US-approved establishments). The cuts are packed in containers, sealed with the health mark and shipping mark. Each piece of meat is vacuumpacked, the film also is marked with the health mark. At the Swiss border every shipment is checked by a Swiss border veterinarian. There is a monitoring program in place to take samples for species testing from all imported meat. The processing establishment receives the original containers. Approved establishments are under continuous supervision. Export production has to be announced to the inspector in advance. In a slaughterhouse there is at least one veterinarian during the whole period of slaughter, in cutting plants and processing establishments there is a daily inspection.

Meat of different species is processed separately, by time or by place.

3. Testing-Ready-to-Eat Product for Listeria monocytogenes and Salmonella species, page 10: The Swiss legislation has a lower limit concerning Listeria monocytogenes for meat products with a water activity < 0.92 (which is the case for ham and air-dried beet): < 100cfu/ g. For Salmonella the Swiss standard is the same as yours: for ready-to-eat products: "not detectable in 25 g". We therefore have a special requirement for the US-approved establishments to assure that the products intended for the US meet FSIS-requirements for Listeria. They all do monitoring on the finished product, and the method for Listeria should be a qualitative one. In case of a positive result, the establishment has to take corrective actions immediately: block the lot the sample has been taken from, start with further investigations. In our Ordinance we have no detailed mandatory procedure. The procedure to withhold the next three lots and test them, is the standard procedure of the Border Veterinary Service.

We take the opportunity to inform you about our discussions with APHIS about their import restrictions put in place February 9, 2001:

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These restrictions are still in place. They ban all meat products from European countries, because APHIS sees a risk of commingling of meat from BSE-free countries and meat from BSE-affected countries in the establishments. Additionally APHIS does not allow meat from FMD-affected countries to be processed in Switzerland nevertheless the processing procedure fulfill the requirement for the import of meat products from FMD-affected countries. As a consequence, beef from Brazil and Uruquay is no longer eligible for export production because of FMD, and Swiss beef is not eligible because of BSE. APHIS does not accept our guarantees with regard to non-commingling. APHIS does not accept the evaluation of our inspection system by your Service as sufficient. We have the situation that there has been no export since the beginning of year 2001, and we are afraid, that it will not change very quickly.

Three of the six establishments, which were approved at the time of the audit, have no longer the intention to be US-approved. We therefore withdrew the approval. The establishments are:

| Est.No. | Name and address | Slaughter | Cutting | Processing |
|---------|---|-----------|---------|------------|
| 121 | Gehrig AG Thalstr. 35 CH-4710 Klus | • | • | • |
| 293 | Rapelli SA Unità produzione Via Lische CH-6855 Stabio | | | • |
| 324 | Rapelli SA, Via Laveggio 13, CH – 6855 Stabio | | | • |

Yours sincerely

DIVISION PERMITS AND INSPECTIONS

The Deputy Head:

Dr J. Schluep

cc:

- US Mission Geneva, Office of Agricultural Affairs, fax 022-749 53 33
- Swiss Embassy, Washington